

Docket No. 7444/73871/GJG/ACK

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Andrzej Lipkowski et al.

Serial No.: 10/524,343 Examiner: Julie Ha.

Filed: January 30, 2006 Group Art Unit: 1654

For : COMPOUNDS AND THEIR ANALGESIC APPLICATIONS

30 Rockefeller Plaza, 20th F1. New York, New York 10112

Mail Stop RCE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

SIR:

DECLARATION UNDER 37 C.F.R. §1.132 OF ANDRZEJ W. LIPKOWSKI

I, Andrzej W. Lipkowski, hereby declare that:

- I am named as an inventor on the above-identified application and I am employed as a Professor at the Medical Research Center, Polish Academy of Sciences, Pawinskiego 5, PL 02-106 Warsawza, Poland.
- 2. I previously made a March 28, 2009 Declaration Under 37 C.F.R. \$1.132 which detailed the results of experiments performed to determine the duration of anti-nociception of each of (1) Tyr-D-Met-Gly-Phe-NH₂; (2) (Tyr-D-Met-Gly-Phe-NH₂-)₂; (3) Tyr-D-Ala-Gly-Phe-NH₂; and (4) (Tyr-D-Ala-Gly-Phe-NH₂-)₂. In the July 6, 2009 Final Office Action,

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the Examiner requested further clarification about the comparable duration of anti-nociception observed for the two monomers, $Tyr-D-Met-Gly-Phe-NH_2$ and $Tyr-D-Ala-Gly-Phe-NH_2$.

- 3. In experiments performed by me or under my supervision using a rat tail-flick model of anti-nociception to determine the duration of anti-nociception of Tyr-D-Met-Gly-Phe-NH₂ and Tyr-D-Ala-Gly-Phe-NH₂, each at a dose of 2 nmol, anti-nociception levels of 0% MPE were observed at 120 minutes post administration for both Tyr-D-Met-Gly-Phe-NH₂ and Tyr-D-Ala-Gly-Phe-NH₂.
- 4. As previously declared, the level of anti-nociception elicited by 0.005 nmol of biphalin was 0% MPE at 120 minutes post administration. However, the level of anti-nociception elicited by 0.005 nmol of the dimer (Tyr-D-Met-Gly-Phe-NH₂-)₂ was 30% MPE at 120 minutes post administration.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made herein on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may

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jeopardize the validity of the subject application or any patent issuing thereon.